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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,000	04/06/2001	Giovanna Tosato	4239-55414	5198

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EXAMINER
DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,000	TOSATO ET AL.	
	Examiner	Art Unit	
	Natalie A. Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-37,48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement has been considered. A signed copy is attached hereto.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-4, drawn to a peptide, classified in class 530, subclass 350.

   II. Claims 5-8, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.

   III. Claims 9-21, drawn to a method of stimulating proliferation of hematopoeitic cells in a subject exposed to chemotherapy or irradiation, classified in class 514, subclass 13.

   IV. Claims 22-30, drawn to a method of stimulating proliferation of hematopoeitic stem cell, classified in class 514, subclass 13.

   V. Claims 31-37, drawn to a method of stimulating proliferation or survival of hematopoeitic stem cell in a subject, classified in class 514, subclass 13.

   VI. Claims 38-47, drawn to a method of protecting bone marrow cells in a subject from toxicity using a peptide, classified in class 514, subclass 13.

   VII. Claim 48, drawn to a method of protecting bone marrow cells in a subject from toxicity using a nucleic acid, classified in class 514, subclass 44.

   VIII. Claim 49, drawn to a method of stimulating hematopoiesis in a subject using a peptide, classified in class 514, subclass 13.

In the event applicant elects Group I or II, claims 10-14, applicant is required to elect a single species of peptide or nucleic acid, comprising:

Species A, drawn to SEQ ID NO: 3

Species B, drawn to SEQ ID NO: 4

Species C, drawn to SEQ ID NO: 5

Species D, drawn to SEQ ID NO: 6

Species E, drawn to SEQ ID NO: 7

Species A-E are patentably distinct based on structural and functional differences and mode of action, as species may target different receptors.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-II(products) and III-VIII (methods) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I, VI may be used for a number of different processes that are very much unrelated. For example, the protein of Group I may not only be used in the methods of Groups III-VI and VIII, but may also be used to isolate an antibody. The nucleic acid of Group II may not only be used in the method of Group VII, but may also be used to synthesize a protein.

2. The products of Groups I-II are structurally and functionally different, are drawn to structurally and functionally different molecules, each invention requires different reagents and steps to make and characterize them, or different methods of use that do not share common steps or reagents and rely on different endpoints.

3. The methods of Groups III-VIII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects. For example, the *in vivo* methods of Groups III, V-VIII require different and steps, reagents and modes of action than the *in vitro* method of Group IV. Likewise, a method of stimulating proliferation, protecting bone marrow cells and stimulating hematopoiesis have different endpoint and effects.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and require different search strategies, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 38-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a bone marrow cell using a peptide comprising amino acids 129-146 or 103-163 of SEQ ID NO: 3, does not reasonably provide enablement for protection using any other peptide comprising at least 18 contiguous amino acids of SE ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

3. Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

4. The nature of the invention is protecting bone marrow cell using a peptide comprising at least 18 consecutive amino acids of SEQ ID NO: 3. The specification discloses two peptide fragments comprising at least 18 consecutive amino acids of SEQ ID NO: 3 (vasostatin), which protects hematopoietic cells from the toxicity of chemotherapeutic agents or radiation or stimulates hematopoeisis. The first comprises 129-146 of SEQ ID NO: 3 and the second comprises amino acids 103-163 of SEQ ID NO: 3 (p. 32). There are many peptide fragments comprising at least 18 consecutive amino acids of SEQ ID NO: 3 that may or may not perform the same functions and the specification does not give any guidance to which peptides will exhibit the biological activities as claimed, or any guidance as to which regions of amino acid sequence are responsible for biological activity and thus, must be preserved so the peptide will function. Thus, it would be an undue burden to one of ordinary skill in the art to assay for

peptide comprising at least 18 amino acids of SEQ ID NO: 3, which is capable of functioning as contemplated. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any peptide comprising at least 18 consecutive amino acids of SEQ ID NO: 3 and applicant has not enabled all of these types of peptides because it has not been shown that these peptides are capable of functioning as that which is being disclosed. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure as to which peptide should be used in the invention. Therefore, in view of the lack of guidance as how to select for the claimed peptide, the unpredictability of other peptides working, and the breadth of the claims, and, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
March 8, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600